

EXHIBIT B

Sheila Weiss Smith, Ph.D., FISPE

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EDUCATION

Postdoctoral fellowship in Pharmacoepidemiology and Regulatory Sciences – 1994-1996

United States Food and Drug Administration, Rockville, Maryland and
University of Maryland Schools of Medicine and Pharmacy, Baltimore, Maryland

Ph.D. in Epidemiology - 1996

The Johns Hopkins University, Baltimore, Maryland
Dissertation: Apolipoproteins and premature cardiovascular disease among middle-aged adults undergoing coronary angiography.
Dissertation advisor: Professor Terri Beaty, Director, Genetic Epidemiology Division, Epidemiology Department, School of Hygiene and Public Health, the Johns Hopkins University, Baltimore, MD.

M.S. in Exercise sciences – 1986

Northeastern University, Boston, Massachusetts
Dissertation: A comparison of arm ergometry with the treadmill for exercise testing of swimmers. May 1986.
Dissertation advisor: Professor Jay Gillespie, Chairman, Cardiovascular Sciences Department, Northeastern University, Boston, MA.

B.S. in Biology – 1981

University of Maine, Orono, Maine

EMPLOYMENT

July 2002- **Associate Professor** Department of Pharmaceutical Health Services Research, School of Pharmacy, Secondary appointment: Department of Epidemiology and Preventive Medicine, School of Medicine, University of Maryland, Baltimore, MD

2005- **Visiting Associate Professor.** Department of Epidemiology, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD (annually, June-July)

1997-2002 **Assistant Professor** Department of Pharmacy Practice and Science, School of Pharmacy, Secondary appointment: Department of Epidemiology and Preventive Medicine, School of Medicine, University of Maryland at Baltimore, Baltimore, MD

1996-1997 **Epidemiologist/Statistician** Epidemiology Branch, Office of Epidemiology and Biostatistics, Center for Drug Evaluation and Research, Food and Drug Administration, Rockville, MD

1994-1996 **Post-doctoral fellow in pharmacoepidemiology** Epidemiology Branch, EB/CDER/FDA, Rockville, MD, Department of Epidemiology and Preventive Medicine, School of Medicine, University of Maryland, Baltimore, MD, and the Department of Pharmacy Practice and Science, School of Pharmacy, University of Maryland, Baltimore, MD

1993-95 **Project Director** JH-CAD Follow-up Study. Lipid Research Unit, Johns Hopkins Medical Institutions, Baltimore, MD

1991-93 **Statistical programmer** Johns Hopkins Medicine Institutions, Baltimore, MD

1992-93 **Consultant epidemiologist** Drug Safety/Epidemiology Division, Hoffman-La Roche AG Basel, Switzerland (Full & part-time)

1989-90 **Senior Research Associate** New England Research Institute, Inc., Watertown, MA

1986-89 **Senior Research Associate** (1988-1989) Research Associate (1987-1988) Senior Research Assistant (1986) American Institutes for Research, Cambridge Research Center, Cambridge, MA

1985-86 **Program Coordinator** Cardiovascular Rehabilitation Exercise Program. Northeastern University, Boston, MA

1983-86 **Exercise Test Technician** Cardiovascular Sciences Division, Department of Physical Education, Northeastern University, Boston, MA

1981-83 **Quality Control Chemist** Amicon Corporation (a division of W.R. Grace), Beverly, MA

PUBLICATIONS

1. Weiss Smith S. The author responds. New Engl J Med 2007;375(24)2521-2522. (letter).
2. Weiss Smith S. Sidelining safety – The FDA’s inadequate response to the IOM report. New Engl J Med 2007;357:960-963.
3. Bollinger ME, Weiss Smith, S, LoCasale R, Blaisdell, C. Transition to Managed Care Impacts Health Care Service Utilization by Children Insured by Medicaid. Journal of Asthma. (forthcoming, accepted June 2007)

4. Weiss Smith S. Chapter Title: Pharmacoepidemiology. In: *Encyclopedia of Epidemiology*. Editor: Boslaugh S. Publisher: Sage Publications Inc. (Expected publication date: October 2007)
5. McPherson ML, Weiss Smith SR, Powers A, Zuckerman IH. Patient's knowledge about medications is associated with diabetes control. *J Res Soc Admin Pharmacy*. (forthcoming, accepted January 2007)
6. Blaisdell CJ, Weiss SR, LoCasale R, Gu A. Risk Areas for Pediatric Acute Care. *Health in Place*. 2007;13:404-416.
7. Weiss Smith S. Summary of Issues: January 17, 2006 IOM Workshop. Commissioned by the IOM Committee on the Assessment of the US Drug Safety System. In: *The Future of Drug Safety: Promoting and Protecting the Health of the Public*. Editors: Baciu A, Stratton K, Burke SP: National Academies Press. 2006. Available at: <http://www.nap.edu/catalog/11750.html>
8. Lee E, Maneno MK, Smith L, Weiss SR, Zuckerman IH, Wutoh AK. National Patterns of Medication Use during Pregnancy. *Pharmacoepidemiol Drug Safety*. 2006;15(8):537-545.
9. Hirshorn JM. Weiss SR, LoCasale R, Levine E, Blaisdell CJ. Looking beyond urban/rural differences: Emergency department utilization by asthmatic children. *J. Asthma* 2006;43(4):301-6.
10. Koro CE, Bowlin SJ, Weiss SR. Antidiabetic therapy and the risk of heart failure in type 2 diabetic patients: an independent effect or confounding by indication. *Pharmacoepidemiol Drug Safety*. 2005;14:1-7.
11. Cluxton RJ, Li A, Heaton PC, Weiss SR, Zuckerman IH, Moomaw CJ, Hsu VD, Rodriguez EM. Impact of labeled hepatic enzyme monitoring for troglitazone and rosiglitazone: Findings from the Ohio State Medicaid program. *Pharmacoepidemiol Drug Safety*. 2005;14:1-9.
12. Zuckerman IH, Weiss SR, McNally D, Layne B, Mullins CD, Wang J. Impact of an educational intervention for secondary prevention of myocardial infarction on Medicaid drug use and cost. *Am J Managed Care*. 2004;10:493-500.
13. Kimes D, Ullah A, Levine E, Nelson R, Timmins S, Weiss SR, Bollinger ME, Blaisdell C. Relationships between pediatric asthma and socioeconomic/urban variables in Baltimore, Maryland. *Health & Place*. 2004;10:141-152.
14. Kimes D, Levine S, Timmins S, Weiss SR, Bollinger ME, Blaisdell C. Temporal dynamics of emergency department and hospital admission of pediatric asthmatics. *Environmental research* 2004;94:7-17.
15. Kimes D, Nelson R, Levine E, Timmins S, Weiss S., Bollinger ME, Blaisdell C. Predicting paediatric asthma hospital admissions and ED visits. *Neural Comput & Applic* 2003;12:10-17.

16. Pradel FG, Weiss SR, Magder LS, Tsoukleris M, Fahlman C, Bollinger ME. Preliminary validation of the Inhalation device skill assessment tool. *J Soc Admin Pharm.* 2003;20:18-24.
17. Amr S, Bollinger ME, Myers M, Hamilton RG, Weiss SR, Rossman M, Osborne L, Timmins S, Kimes DS, Levine ER, Blaisdell CJ. Environmental allergens and asthma in urban elementary schools. *Ann Allergy, Asthma, Immunol.* 2003;Jan;90(1):34-40.
18. Moore TJ, Weiss SR, Kaplan S, Blaisdell C. Reported adverse drug events in infants and children under 2 years of age. *Pediatrics* 2002;Nov;110(5):e53.
19. Koro CE, Fedder D, L'Italien GJ, Weiss SR, Magder LS, Kreyenbuhl, J, Revicki, D, Buchanan, RW. Assessment of the independent effect of Olanzapine and Risperidone exposure on the risk of hyperlipidemia in schizophrenia patients. *Arch Gen Psychiatry* 2002;Nov;59:1021-1026.
20. Lee E, Zuckerman IH, Weiss SR. Patterns of Pharmacotherapy and counseling for osteoporosis management in visits to United States Ambulatory Care physicians by women. *Arch Intern Med* 2002; Nov 11;162 (20):2362-2366.
21. Blaisdell C, Weiss SR, Kimes DS, Levine ER, Myers M, Timmins S, Bollinger MB. Using seasonal variations in asthma hospitalizations in children to predict hospitalization frequency. *J Asthma.* 2002; Oct;39(7):567-75.
22. Koro CE, Fedder D, L'Italien GJ, Weiss SR, Magder, LS, Kreyenbuhl, J, Revicki Dam Buchanan RW. An assessment of the independent effect of Olanzapine and Risperidone on the relative risk of diabetes in schizophrenic patients. *BMJ.* 2002;325: (7358):243.
23. Weiss SR, Zuckerman I, Hsu V, Huang X. Factors influencing use and compliance with estrogen replacement therapy. *J Womens Health Gender-based Med.* 2001;10 (8):811.
24. Manson JM, McFarland B, Weiss S. Evaluation of markers for early detection of pregnancy in an automated database. *Am J Epidemiol* 2001;Jul 15;154(2):180-7.
25. Zuckerman IH, Stuart B, Magder L, Bollinger ME, Weiss SR. Adherence to asthma treatment guidelines among children in Maryland Medicaid. *Curr Ther Res Clin Exp* 2000;61:912-924.
26. Weiss SR. Prescription medication use in pregnancy. *Medscape Pharmacotherapy* November 15, 2000. Available at:
<http://www.medscape.com/Medscape/pharmacology/journal/2000/v02.n06/mp7387.weis/mp7387.weis.html>
27. Weiss, SR, Cooke CE, Bradley LR, Manson JM. A Pharmacist's Guide to Pregnancy Registry Studies. *J Am Pharm Assoc* 1999;39:830-4.
28. Weiss SR, McFarland B, Burkhart G and Ho PTC. Cancer recurrences and second primary

cancers after use of prescription antihistamines or antidepressants. Clin Pharmacol Ther 1998;63(6):594-9.

29. Weiss, SR, Bachorik PS, Becker LC, Moy TF, and Becker DM. Lipoprotein(A) and coronary heart disease in a racially mixed population: The Johns Hopkins Sibling Study. Ethn Dis. 1998;8(1):60-72.
30. Burkhardt G, Brown N, Griffin M, Ray W, and Weiss, SR. Angiotensin-converting enzyme inhibitor-associated angioedema: Higher risk in blacks than whites. Pharmacoepidemiology and Drug Safety 1996;5:49-154.
31. Brambilla DJ, McKinlay SM, McKinlay JB, Weiss, SR, Johannes CB, Crawford SL and Longcope C. Does collecting repeated blood samples from each subject improve the precision of estimating steroid hormone levels? J Clin Epidemiol 1996;49:345-350.
32. Washburn RA, Smith KW, Goldfield (Weiss) SRW, and McKinlay JB. Reliability and physiologic correlates of the Harvard Alumni Activity Survey in a general population. J Clin Epidemiol 1991;44(12):1319-26.
33. Longcope C, Goldfield (Weiss) SRW, Brambilla DJ and McKinlay JB. Androgens, estrogens and sex hormone-binding globulin in middle-aged men. J Clin Endocrinol Metab 1990;71:1442-1446.
34. Longcope C, Herbert PN, McKinlay SM and Goldfield (Weiss) SRW. The relationship of total and free estrogens and sex hormone-binding globulin with lipoproteins in women. J Clin Endocrinol Metab 1990;71:67-72.
35. Washburn RA, Goldfield (Weiss) SRW, Smith KW and McKinlay JB. The validity of self-reported exercise-induced sweating as a measure of physical activity. Am J Epidemiol 1990;132:107-13.

GUIDANCE, TECHNICAL REPORTS, AND NEWSLETTER ARTICLES

Weiss Smith S, Donovan M. Perinatal session at the 21st ICPE. Scribe. 2005;8(5):5.

Weiss Smith S, Jones T. A New Training Option at the University of Maryland. Scribe 2004;7(2):5.

Weiss SR A flawed example. J Am Pharm Assoc 2000;40(5):580-581. (Letter)

Weiss SR, Palumbo FB. The University of Maryland's Center on Drugs and Public Policy. J Managed Care Pharmacy. 2000;6(2):184-185. (Invited)

Manson JE, Weiss SR. Industry guidance document: Pregnancy Registries. (Principle draft) Pregnancy labeling taskforce technical report. Food and Drug Administration. 1999.

Weiss SR, Merchant S. Federal databases for pharmaceutical research. Technical Report. Research Monitoring Review 1997;1(3)1-13.

Weiss SR, Vega A, McCloskey C, McFarland BE, Corelle C, Maynard C. Prescription drug use during pregnancy among women in KPNW, 1993-1994. Epidemiology Branch/CDER Technical report. Food and Drug Administration. 1997.

Anthony, M, Weiss SR, and Burkhart G. Reviewers' Guidance Document. Human pregnancy data: Pregnancy Registries. (Principle draft) Pregnancy labeling taskforce technical report. Food and Drug Administration. 1996.

PRESENTATIONS - invited

1. Weiss S.R. and Gogolak V. Assessing the Value of Data Mining. SETS: Joint Industry-Government working group on data mining and pharmacovigilance. Via webex. September 12, 2007.
2. Weiss S.R. Pharmacovigilance and Data Mining. In: Introduction to Epidemiology. Yale University School of Public Health. New Haven, CT. February 20, 2007.
3. Weiss S.R. Improving the U.S. Drug Safety System: Data Mining for Adverse Events. Bloomberg School of Public Health, Johns Hopkins University. Baltimore, MD. February 12, 2007.
4. Weiss SR. Introduction to Risk Management. In: 4th Annual Conference on Risk Management. Philadelphia, PA. October 24-25 2005. (Chairperson).
5. Weiss S.R. Impact of targeted pharmaceutical risk management efforts. In: Risk Communication RiskMAP Workshop. Washington D.C. May 2-4, 2005.
6. Weiss S.R. Cohort studies in pharmacoepidemiology: Exposure-based registries. In: Introduction to Epidemiology. Yale University School of Public Health. New Haven, CT. February 15, 2005.
7. Weiss S.R. Use of registries and other observational studies to investigate safety signals. In: 4th annual workshop for contemporary pharmacovigilance and risk management strategies. Drug Information Association. Washington DC. January 23-27, 2005.
8. Weiss S.R. Approaches to quantifying the risk:benefit balance. FDA Visiting Lecture. Rockville, MD. January 11, 2005.
9. Weiss S.R. Assessing benefits and risks: Vioxx. In: Vioxx: What went wrong? What went right? Drug and Device Dialogue. November 10, 2004.
10. Weiss SR. Quantitative approaches to benefit-risk assessment. In: Assessing benefit, risk and a benefit-risk balance conference. Philadelphia, PA. October 2004.
11. Weiss SR, Burkhart GA. Person-time case control study design. International Society of Pharmacoepidemiology annual meeting. Philadelphia, PA. August 2003.
12. Weiss SR. Strategies for the postmarketing environment. Henry Stuart Conference. Washington DC. May 22, 2003.
13. Weiss SR. Use of antidiabetic therapy and the risk of health failure among type 2 diabetics. University of Maryland School of Medicine Visiting Lecture Series, Department of Epidemiology and Preventive Medicine, Baltimore, MD. April 3, 2003.
14. Weiss SR. Cohort studies in Pharmacoepidemiology: Exposure-based registries.

“Introduction to Pharmacoepidemiology” Course, Yale University School of Medicine, Department of Epidemiology and Public Health. New Haven, CT. February 18, 2003.

15. Weiss SR. Postmarketing surveillance of drug use in pregnancy. “Meeting FDA, EPA, OECD and ICH Regulatory Requirements for Reproductive Toxicology Data Submissions” Henry Stuart Conference. Washington DC. May 10, 2002.
16. Weiss SR. Cohort studies in Pharmacoepidemiology: Exposure-based registries. “Introduction to Pharmacoepidemiology” Course, Yale University School of Medicine, Department of Epidemiology and Public Health. New Haven, CT. February 13, 2001.
17. Weiss SR. Registries and observational designs: An overview. Drug Information Association Workshop on Adverse Experience: Post Marketing Surveillance in the New Millennium. Washington DC. Jan 8-10, 2001.
18. Weiss SR and Zuckerman I. Childhood asthma in Maryland Medicaid. Regional Asthma Surveillance Workshop. Baltimore, MD. September 19, 2000.
19. Weiss SR. Introduction to pregnancy registries. International Society of Pharmacoepidemiology Annual Meeting. Barcelona, Spain. August 2000.
20. Weiss SR. Evaluating the safety of pharmaceuticals in pregnancy. Organization of Teratogen Services/Teratology Society Joint Annual Meeting. West Palm Beach, FL. June 2000.
21. Weiss, SR. Phase IV studies: Registries and other forms of active surveillance. Drug Information Association Annual Meeting, San Diego, CA. June 14, 2000.
22. Weiss SR. The uses and importance of the National Ambulatory Medical Care Survey (NAMCS) Data. United States Census Bureau Training Conference for NAMCS and NHAMCS program staff. Arlington, VA. September 1999.
23. Weiss SR. Postmarketing Risk Assessment: Registries and other forms of active surveillance. DCTDA Training Seminar Series, CBER, Food and Drug Administration. Rockville, MD July 1999.
24. Weiss SR, Zuckerman I, Cooke CE, Hsu VD, Huang, X. Estrogen replacement therapy use in Maryland Medicaid. American Association of Colleges of Pharmacy Annual Meeting, Boston, MA July 1999. (Poster) *This poster was also presented at the Aging Research Poster Day sponsored by the University of Maryland Center for Research on Aging, February 2000.*
25. Weiss SR, Zito J, and Qi, S. Treating women with depression in ambulatory care. University of Maryland School of Medicine Visiting Lecture Series, Department of Epidemiology and Preventive Medicine, Baltimore, MD. 1998.
26. Weiss SR. Use of administrative databases for monitoring drug effects during pregnancy, Drug Information Association Annual Meeting, Boston, MA 1998.

27. Weiss SR. Adjusting for co-morbidities in outcomes research. ESAS Research Roundtable, APhA Annual meeting, Miami Beach, FL. 1998.
28. Weiss SR, McFarland BE, Vega A, McCloskey C, and Correlle C. Prescription drug use in pregnancy in KPNW, 1993-1994. Staff College Seminar Program, FDA, Rockville, MD 1998.
29. Weiss SR. Pharmacoepidemiology and adverse drug events. Study Tour in Hospital Formulary Development & Drug Utilization Review, as part of the Rational Pharmaceutical Management Project of the Health Financing and Sustainability Project. Baltimore, MD 1997.
30. Weiss SR. Could cigarette smoking explain racial differences in lipoprotein(a) concentration? Clinical Pharmacology Seminar, Uniformed Services Health Sciences University, Bethesda, MD. 1996.
31. Weiss SR and Burkhart GA. Angiotensin-converting enzyme inhibitor-associated angioedema: Higher risk in blacks than whites. University of Maryland School of Medicine, Department of Epidemiology and Preventive Medicine Visiting Lecture Series, Baltimore, MD. 1996.
32. Weiss SR, Rosa F, Conrad T, Frieman J, and Kweder S. Prescription drug use during pregnancy. International Society for Pharmacoepidemiology annual meeting, Montreal, Quebec. 1995.
33. Weiss SR, Rosa F, Conrad T, Frieman J, and Kweder S. Prescription drug use during pregnancy in Medicaid: Directions for further research. Food and Drug Administration, CDER Grand Rounds, Rockville, MD. 1995.
34. Weiss SR, Rosa F, Conrad T, Freiman J, and Kweder S. Prescription drug use during pregnancy. Pharmacy Graduate Seminar Series, Pharmacy practice and science department, University of Maryland School of Pharmacy, Baltimore, MD. 1994.

SELECTED PRESENTATIONS – peer-reviewed

Weiss-Smith, S., Gogolak, V., Deshpande, G., Chung, S., & Mehta, S. Missing data in FDA adverse event reporting system. Pharmacoepidemiology and Drug Safety, 2007;16:S72. International Society of Pharmacoepidemiology Annual Meeting, Quebec City August 2007.

Gogolak, V., Weiss-Smith, S., Chung, S., & Deshpande, G. (2007). Signal volume: Thresholds and statistics create huge differences. Pharmacoepidemiology and Drug safety, 2007;16:S258. . International Society of Pharmacoepidemiology Annual Meeting, Quebec City August 2007. (Poster)

Deshpande, G., Weiss-Smith, S., Tommasello, A., Simoni-Wastila, L., & Gogolak, V. (2007). Characteristics of adverse event reporting for narcotic and non-narcotic analgesics.

Pharmacoepidemiology and Drug safety. 2007;16:S260. . International Society of Pharmacoepidemiology Annual Meeting, Quebec City August 2007. (Poster)

Weiss SR, LoCasale R. Adverse Drug Events among the Elderly. International Society of Pharmacoepidemiology Annual Meeting. Nashville, TN. August 2005. (Poster)

Zuckerman IH, Weiss SR, McNally DL, Layne B, Mullins CD, Wang J. Impact of an Outpatient physician education program on beta-blocker usage for secondary prevention of myocardial infarction. International Society of Pharmacoepidemiology Annual Meeting. Bordeaux, France. August 2004. (Poster)

SR Weiss, PK Singhal, F Pradel, I Zuckerman, H Rubin, ME Bollinger, C Blaisdell, B Stuart. Environmental Factors and Quality of Life among Poor Children with Asthma. AAAAI Annual Meeting. San Francisco, CA. March 2004.

Weiss SR. Gu A, Zuckerman IH, Blaisdell C. Change in the weather as a trigger for children's asthma attacks: Who is susceptible? Geomed 03. Baltimore, MD October 2003.

Weiss SR. Summarizing Results of Heart Failure Outcomes Research. In: Mullins CD, Weiss S, Fulda T. Challenges in performing meta-analysis in heart failure outcomes research: Workshop at International Society for Pharmacoeconomics and Outcomes Research Annual Meeting. Arlington, VA. May 2001.

Weiss SR, Doshi, J. Revisiting the safety of SSRI's in pregnancy: A meta-analysis. International Society of Pharmacoepidemiology Annual Meeting. Barcelona, Spain. August 2000. (Poster)

Weiss SR, Zuckerman, I, Hsu V. The use of gastrointestinal agents in long-term care facilities. International Society of Pharmacoepidemiology Annual Meeting, Boston, MA 1999. (Poster) Pharmacoepidemiology and Drug Safety. 1999;8:S36.

Weiss SR, Zito J, and Qi, S. Changes in the treatment of women with depression in the United States: The National Ambulatory Medical Care Survey, 1992-1996. International Society of Pharmacoepidemiology Annual Meeting, Berlin 1998. Pharmacoepidemiology and Drug Safety. 1998;7:S167.

Weiss SR, McFarland BE, Corelle C, Vega, A and McCloskey C. Patterns of drug use in pregnancy. Sigma Chi Poster Session, FDA Regulatory Science Forum, Bethesda, MD 1997. (Poster)

Weiss SR, McFarland BE, Corelle C, Vega A, and McCloskey. Patterns of drug use in pregnancy. International Society of Pharmacoepidemiology annual meeting, Orlando, FL 1997. Pharmacoepidemiology and Drug Safety. 1997;6:S69.

Weiss SR, Bachorik PS, Becker LC, Hoch JS, Moy TF, and Becker DM. Current smoking status and levels of Lp(a) in black and white siblings of persons with premature coronary disease. American Heart Association annual meeting, New Orleans, LA. 1994.

Weiss SR, Longcope C, Brambilla DJ, and McKinlay JB. Cigarette smoking and serum steroid hormone levels in men: results from the Massachusetts male aging study. International Conference

on the Menopause, Bangkok. 1990.

Weiss SR, Physical activity and attitudes toward exercise. Future of Adult Life International Conference, Amsterdam. 1990.

Weiss SR, Washburn R, and Smith K. Reliability and validity of the Paffenbarger physical activity instrument. American Public Health Association annual meeting, Boston, MA. 1988.

SELECTED GRANTS AND CONTRACTS

Funded-Research

Principal Investigator

Title: A critical evaluation of data mining.
CoPrincipal Investigator: Victor Gogolak
Sponsor: PhRMA

Title: Review Article on Assessing the Population Impact of Common Pharmaceuticals and Nutraceuticals on the Burden of Cancer
Sponsor: National Cancer Institute

Title: An assessment of the independent effect of oral antidiabetic agents and insulin exposure on the risk of heart failure in type 2 diabetic patients.
Sponsor: GlaxoSmithKline

Title: A research-training program for pharmacy-school graduates: Medication usage in pregnancy and lactation.
Co-Investigators: Ilene Zuckerman and David Mays
Source: Gustavus and Louis Pfeiffer Research Foundation

Title: Compliance with liver testing guidelines by health care professionals.
Co-Investigators: Ilene Zuckerman
Source: Food and Drug Administration

Title: Estrogen replacement therapy use in Maryland Medicaid.
Co-Investigators: Catherine Cooke, Ilene Zuckerman
Source: New Investigators Program for Pharmacy Faculty, American Association of Colleges of Pharmacy

Title: National trends in the treatment of depression in women
Co-Investigator: Julie Zito
Source: The Women's Health Research Group, School of Medicine, University of Maryland

Title: Prescription drug use during pregnancy in an HMO population.
Co-Investigators: Amarylis Vega, Bentson McFarland
Source: Office of Women's Health, FDA. Intramural research grant

Title: Apolipoproteins and Cardiovascular Disease.

Co-Investigators: NA

Source: Department of Epidemiology, the Johns Hopkins University. Doctoral research grant

Co-Investigator

Title: Effect of Practice Guidelines on care of chronic kidney disease in the VHA

Role: Investigator

Principal Investigator: Jeffrey Fink, MD, MS

Role: Investigator

Source: NIH

Title: Outcomes, Quality of Care, and Costs of Chemotherapy in Prostate and Lung Cancer

Role: Investigator

Principal Investigator: C. Daniel Mullins, PhD

Source: Sanofi-Aventis

Title: Use and Outcomes of Novel Chemotherapeutic Agents in Colorectal Cancer

Role: Investigator

Principal Investigator: C. Daniel Mullins, PhD

Source: Sanofi-Aventis

Title: The University of Maryland DeCIDE Center

Role: Director, Methods and Statistics Core

Principal Investigator: Bruce Stuart

Source: AHRQ

Title: Identifying environmental correlates of an asthma epidemic in children.

Role: Co-PI

Principal Investigator: Carol Blaisdell (Medicine)

Source: HCFA

Title: Identifying environmental correlates of an asthma epidemic in children.

Role: Investigator

Principal Investigator: Carol Blaisdell (Medicine)

Source: NASA

Title: Annotated bibliography for treatment of congestive heart failure.

Role: Co-PI

Principal Investigator: C. Daniel Mullins

Source: US Pharmacopoeia

Title: Epleronone cost-effectiveness analysis.

Role: Investigator

Principal Investigator: C. Daniel Mullins

Source: Pharmacia

Title: Alpha-1-Antitrypsin Deficiency cost of illness model.

Role: Investigator

Principal Investigator: C. Daniel Mullins

Source: Alpha One Foundation

Title: Impact of MCO Policy on Quality of Pediatric Asthma Care.

Role: Investigator

Principal Investigator: Bruce Stuart

Source: Agency for Health Care Policy and Research

Title: Maryland Drug Use Review.

Role: Epidemiologist

Principal Investigator: Ilene Zuckerman

Source: Department of Hygiene and Mental Health, State of Maryland

Title: Pennsylvania Drug Use Review.

Role: Epidemiologist

Principal Investigator: Ilene Zuckerman

Source: Department of Health, Commonwealth of Pennsylvania

Title: Utilization and cost of IVIG therapy for Primary Immune Deficiency Diseases.

Role: Investigator

Principal Investigator: C. Daniel Mullins

Source: Immune Deficiency Foundation

Funded-Service/Other

Title: Predoctoral Fellowship Grant.

Role: Principal Investigator

Source: Drug Information Association

Title: Postdoctoral Fellowship Grant.

Role: Principal Investigator

Co-Investigator: C. Daniel Mullins

Source: Drug Information Association

Title: The Fifth Wintergreen Conference on Outcomes Research in Pharmacy.

Role: Principal Investigator

Co-Investigators: Pat McKercher and Frank Palumbo

Source: The Outcomes Research Group, Pfizer Pharmaceuticals

Title: Pharmaceutical Research Monitoring Project.

Role: Co-Investigator, 10% effort

Principal Investigator: Frank Palumbo

Source: Merck, Novartis, Pfizer, Pharmacia-Upjohn, and Wyeth-Ayerst

Funded-Internal

Title: Asthma self-management and caregiver expectations among children with asthma.

Role: Principal Investigator (20% effort)

Co-investigator: Pradel F.

Source: PHSR department

Title: Evaluating the Maryland's HealthChoice Encounter data for creating a pregnancy registry.
Role: Principal Investigator (10% effort)
Co-investigators: Zuckerman I and Manson J
Source: School of Pharmacy

DOCTORAL STUDENTS ADVISED

Sigal Kaplan (2004) Dissertation title: The relationship between blood pressure and bone mineral density. (Funded by a grant from the Women's Health Research Group, University of Maryland School of Medicine)

Jesse Lee Cooke, Jr. (2005) Dissertation title: Breast cancer patients' preferences for local and systemic therapy and willingness to participate in clinical trials. (Funded by an individual dissertation training grant from NIH-NCI)

Robert LoCasale (2007) Dissertation title: Trends and implications of polypharmacy: A case study. (Funded a individual dissertation training grant from NIH-NIMH)

Meaghan St. Charles (2007) Dissertation title: Gastroenterologists prescribing of infliximab for Crohn's disease: A national survey.

PROFESSIONAL ORGANIZATIONS/MEMBERSHIPS (current/past)

- American Association of Colleges of Pharmacy
- Drug Information Association
- International Society of Pharmacoepidemiology (Board of Directors 2004-2006, Fellow)
- Kappa Delta Pi (honor society in education)
- Rho Chi (honor society in pharmacy)

SELECTED SERVICE ACTIVITIES

University of Maryland

Member, Dean of School of Public Health Search Committee 2006-2007

Faculty affairs committee, School of Pharmacy 2004-2006, 2006-2008 (Chair 2005-06)

MPH program steering committee member (School of Medicine) 2004-2005

Chair, Financial Aid Committee, School of Pharmacy (School of Pharmacy), 2002 - 2003

Graduate Council of the University of Maryland Graduate School, 2001-2003 (Chair, Long-Range Planning and New Program Committee 2002-2003)

Executive committee, Women's Health Research Group (School of Medicine), 2000 –2005.

External

CERTS Think Tank. Creating a national active surveillance network. Program participant. 2007

International Society of Pharmacoepidemiology – Board of Directors (2004-2006), Academic Council, Representative for North America (1999-2001), Chair of Academic Council (2000-2001), Scientific committee member.

FDA - special government employee (expert) 1994-96, 1997-1999, 2000 – 2004, 2005-
 NIH - Pharmacologic working group, Research on women's health for the 21st century, Office of Women's Health, NIH, Bethesda, MD 1997-98 (helped to draft two sections of the final report)
 CDC - Review and comment on the data collection forms for the 2001-2004 NAMCS and NHAMCS surveys conducted by the National Center for Health Statistics, 1999
 CDC/FDA/NIH – Concepts & Strategies to Actively Monitor the Risks of Medications in Pregnancy: Enhancing Post-Marketing Surveillance. Workshop participant. Nov. 29-30, 2000. Bethesda, MD.
 Drug Information Association - Co-chair of poster sessions at annual meetings, 1999-2001
 NASA – Goddard Space Flight Center Earth Sciences (GES) Distributed Active Archive Centers (DAAC) Users Working Group Member. 2000-2002

Review activities

Editorial board: Research in Social and Administrative Pharmacy, 2004-

Peer Reviews: American Journal of Pharmaceutical Education, British Medical Journal, Drug Safety, International Clinical Psychopharmacology, Journal of the American Pharmaceutical Association, Journal of Managed Care Pharmacy, Lancet, Medical Care, Pharmacoepidemiology and Drug Safety, Reproductive Toxicology.

Grant reviews:

- Agency for Healthcare Research & Quality (AHRQ) – special emphasis panel for evaluation of CERTS proposals) 2007
- European Medicines Agency (EMA) – extramural grants reviewer 2006
- FDA Intramural grant review committee member, internal 1995, 1997, external 1998, 1999
- WHRG Intramural grant review committee member, 1999-2005

Consulting

Isotretinoin Scientific Advisory Board 2005-
 Institutes of Medicine 2005-06, Abt Associates 2005-2006, Fulbright & Jaworski 2002-2006, Covance 2002-2005, Luvera, Barnett, Brindley, Beninger & Cunningham, 2000-2002, Robins, Kaplan, Miller & Ciresi LLP, 1999-2002, the Los Angeles Times, 1998-2000, Immune Deficiency Foundation 1998, Parexcel 1998, Medtap Systems, LLC 1997, Hoffman-LaRoche AG 1992-1993
 Expert consultant on several NIH/AHQAR grants in drug safety/pharmaceutical regulation.

REV. 12/2007